EXHIBIT A

migration, tilt, fracture, and perforation, all of which Ms. Booker suffered. It's also the fact that there's a cascade of complications when three happen together like they happened in Ms. Booker. And you'll be able to evaluate the evidence that Bard did not warn adequately about the interaction of these events and how one can lead to the next with harmful effects. 01:50:05 01:50:27

Let's look at each one individually. This is a still shot of the video that you've just seen with the filter placed in the vena cava. And when a filter tilts, it loses its centering. And the testimony will show when these are placed, they need to stay centered, and they need not to move. They can become embedded in the vena cava wall when they tip. It can change the blood flow and it can lead to fractures, migration, perforation, clot creation, and something called caval thrombosis. 01:50:46 01:51:06

Migration, there are two different kinds, one called cephalad, which is a fancy word for towards the heart, and one for caudal, which is a downward movement. So the filter can migrate north, so to speak, up towards the heart, or downward towards the feet. Ms. Booker suffered from a caudal migration but she also suffered from tilt migration, fracture, and perforation. As I've said, the evidence will show that a tilt can lead to those future failures. 01:51:23

I have another animation to show you that Greg will

help with. 01:51:47

So this animation actually shows a tilt and a 01:51:48
fracture with the filter tipping embedding in the side of the
caval wall. The evidence will show when this happens, there
can be a lack of efficacy and the pressure on the components
can lead to a fracture. Again, largest vein in the body 01:52:14
returning blood to the heart. Sheri suffered a fracture and,
as I explained, it traveled to her heart.

Sheri also suffered from a perforation. This depicts
the filter tilting, embedding, and perforating through the side
of the vena cava wall. 01:53:43

And as I pointed out earlier, right next to the vena
cava is the aorta which also appeared -- Sheri Booker's aorta,
and this is actually an overlay of Sheri's x-ray showing the
tip, the tilt and the perforation to her aorta.

The evidence will show that when it comes to these 01:54:18
problems, Bard conducted bench testing starting with its first
retrievable filter, the Recovery filter. And when I refer to
bench testing, a bench is simply a piece of furniture in the
lab where the equipment sits and laboratory testing, you'll
hear throughout the trial through testimony and documents. 01:54:38

director from Bard. He was there from 2004 through 2008 or '9 02:19:14
but he was there during the period.

MR. NORTH: My only correction is he's still employed there today.

MR. LOPEZ: Oh. Okay. 02:19:28

THE COURT: You can begin playing the deposition.

This should be on your screen, ladies and gentlemen and you should be able to hear it.

(Whereupon, videotaped deposition of Dr. David Ciavarella was played for the jury.) 02:20:52

THE COURT: All right. Let's stop the deposition at this point.

Latches, we'll take the afternoon break. We will plan to resume at a quarter to three. We'll excuse you at this time. 02:29:46

(Jury departs at 2:29.)

THE COURT: Counsel, let me remind you of what I said in an order that came out last week. We're not having the court reporters transcribe what is being played on the deposition. So you should be sure to put in the record an 02:30:22
agreed-upon statement of what portions of the depositions were read so that it's clear on appeal.

This portion we just watched showed a document which the jury has seen and it was asked about. There's been no discussion that I know of moving that into evidence. If so, 02:30:40

THE COURT: Cross-examination.

MR. NORTH: Actually, could we put the last exhibit up, 1295.

And could we display it to the jury, Your Honor?

THE COURT: You may.

C R O S S - E X A M I N A T I O N

BY MR. NORTH:

Q Good afternoon, Dr. McMeeking.

A Afternoon.

Q You and I have met on previous occasions.

A Yes, we have.

Q Before -- since we were on this subject, before we go off

of this subject, what Mr. Graves says towards the end is, "The bigger question, is 12 times more resistant enough?"

Isn't that what that document says?

A That's correct.

Q And doesn't it appear he's questioning, okay, we found it is 12 times better, but is that enough? Should we go further?

A That's what he writes in the document.

Q Thank you.

MR. NORTH: That's all with that document.

BY MR. NORTH:

Q Dr. McMeeking, based upon your deposition in this proceeding, it is my understanding that you are not going to offer any opinion here that Bard had a higher rate of any particular type of complication relative to its filters than any other manufacturers; correct?
A No, I'm not here to testify on that.
Q And so you're not here to testify to the relative rates of complications of one filter versus another?
A That's correct.
Q And you're not here to testify as to the relative complications of one Bard filter against another Bard filter?
A No. I'm not here for that purpose.
Q Dr. McMeeking, you have not written any publications during your lengthy career on IVC filters specifically; correct?

A That's correct.
Q And the few publications that you have written that even deal with medical devices concern heart valves; right?
A That's correct.
Q And you have never personally designed a medical device.
A No, I have not.
Q Therefore, you've never designed an inferior vena cava

exhibits that will be appearing in the video that I would like to read off and move into evidence. 04:07:17

Trial Exhibit 2244, which is D'Ayala Exhibit Number 2 at his deposition; Trial Exhibit 2057 is Exhibit 3 to his deposition; trial Exhibit 994, which is Exhibit Number 4 to his deposition; Trial Exhibit 2321, which is Exhibit Number 8 to his deposition; and Trial Exhibit 1001 which is Exhibit 13 to his deposition. 04:07:36

THE COURT: And are you moving those into evidence?

MS. REED ZAID: Yes, sir. 04:07:58

THE COURT: Any objection?

MS. HELM: No, Your Honor.

THE COURT: All right. Those exhibits will admitted. And you may play the deposition.

(Exhibit Numbers 2244, 2057, 994, 2321, 1001 were admitted into evidence.) 04:08:04

MS. REED ZAID: Thank you.

(Whereupon the deposition of Dr. D'Ayala was played.)

THE COURT: All right. Counsel. Let's stop the video there. 04:19:47

All right. We are at 4:20, ladies and gentlemen. We will plan to begin tomorrow morning at nine and we will excuse the jury at this time.

(Jury departs at 4:20.)

THE COURT: Please be seated. 04:20:22

All right. Counsel, without any adjustment for the 04:20:41
portion of Hudnall that was played this morning or for
Dr. D'Ayala's deposition, plaintiff has used 15 hours and 14
minutes; defense has used four hours and 50 minutes, five zero.
Are we still planning tomorrow morning to talk about 04:21:02
the FDA letter?

MS. REED ZAID: Yes, Your Honor.

THE COURT: Okay. So I'll be ready for that.

MS. HELM: Your Honor, I can give you the agreed-upon
adjustments for the Hudnall and Cohen depositions. Hudnall was 04:21:10
finished this morning and Cohen was played this morning.

THE COURT: Okay.

MS. HELM: It's a total of five minutes that goes to
the defendants.

THE COURT: Okay. So that would mean defendants have 04:21:24
used four hours and 55 minutes and plaintiffs have used 15
hours and nine minutes.

All right. Any other matters we need to take up

information on this 510(k).

Q And what did the FDA do in terms of clearance with this particular device -- submission?

A So this 510(k) submission was cleared.

MR. NORTH: Could we display 5353, please.

BY MR. NORTH:

Q Is this a copy of a clearance letter regarding the jugular delivery system?

A Yes, it is.

MR. NORTH: At this time we would tender 5353.

MR. JOHNSON: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5353 admitted.)

BY MR. NORTH:

Q And is 5353 a copy of that clearance letter?

A Yes, it is.

Q What was the date of that letter?

A November 25, 2005.

Q Now, was there a fourth 510(k) submitted related in some way to the G2?

A Yes, there was another, I believe it was a Special 510(k)

for a change to the spline system.

MR. NORTH: Could we display 5361, please.

BY MR. NORTH:

Q Is this a copy of that Special 510(k) concerning the spline system?

A Yes, it is.

Q Could you enlighten us and tell us, if you know, what a spline system is.

A So it's part of the mechanism once again that's used to deliver the filter. So it's not a change to the filter itself, it's a change to the actual delivery mechanism.

Q At the time -- do you recall when this -- what was the date of this submission?

A September 25th, 2006.

Q At that point in time, if the FDA had any concerns about the G2 filter's performance itself or about its labeling, could the FDA have done something in the context of reviewing this 510(k)?

A Yes. As I mentioned for the last 510(k), FDA would use a new device as an opportunity to ask any questions about an existing device if it had any concerns.

Q And what did the FDA do in response to this?

A So this 510(k) was also cleared without any questions.

MR. NORTH: If we could show 5362, please.

And what does table 2 present as a part of the SIR guidelines?

A Table 2 represents other trackable events. And as I had

mentioned earlier, these would be events which, for completeness of the paper, we included. They may have been associated in the world literature with an event from a patient or they may be things which were observed scientifically, but the patient had suffered no injury and had no symptoms or signs.

Q And, again, did you look at -- did you and your committee look at the medical literature to determine the reported rates for each of these trackable events?

A Yes, we did.

Q And what did you determine was the reported rate for fracture of filters?

A The reported rate for fracture was between 2 and 10 percent.

Q Did you determine a reported rate for migration?

A Yes. Between zero and 18 percent.

Q And did you determine a reported rate for IVC penetration?

A Yes. Zero to 41 percent.

Q Did your committee -- did you and your committee make any

observations as to whether penetration and migration events were customarily significant from a clinical perspective?

A The committee recognized, since it was composed of practicing interventional radiologists, that these are commonly observed events, seen when inferior vena cava filters are used.

Q Do you know what -- in determining the reported rates for filter fracture, what medical articles you cited for that?

A Well, originally there were many articles referred to, and two articles were cited here on table 2 for filter fracture, references number 17 and 24.

MR. NORTH: Could we look at the final page at what those articles were, the citations.

Let's go back one page, please.

BY MR. NORTH:

Q What is citation 17 that the committee cited as a basis for -- one of the bases for the reported rates for fracture of 2 to 10 percent in filters?

A That would be the article written with the first author, Dr. Ernest Ferris, and others, titled Percutaneous Inferior Vena Cava Filters, a Followup of Seven Designs in 320 Patients.

guidelines?
A It is slightly higher because, as we've seen previously, the range was cited as up to 10 percent. And that is basically because the committee felt in viewing ranges that the most common range that we observed was up to approximately 10 percent. So it is slightly higher in the exact number.
Q Did the Ferris article in table 2 also discuss various rates of -- reported rates of IVC penetration by various filters?
A Yes, it did.
Q And what did it report to be the penetration rate for the Simon Nitinol filter?
A The Simon Nitinol filter penetration rate is reported at 33 percent.
Q And, again, what did the SIR guidelines that you

spearheaded the development for, what did they report as the reported rate for IVC penetration?
A That range, as I remember from our previous table, this number in the -- in the range reporting.
Q Were these complications and trackable events that you reported about in the SIR guidelines, were they known to you in the medical community prior to developing those guidelines?

A Yes, they were.
Q Are those, the potential for those complications and adverse events, taught to residents and fellows as a part of their medical training?
A They are, and I was one of those persons, since I've worked in academic hospitals, who had the privilege of working with residents and fellows and trainees. And so we would go through these numbers and this data with them to help with teaching.
Q What happened once your committee developed a draft of these guidelines?
A Once a draft was produced by the committee -- and I might say this method included telephone conversations, in-person meeting at two national annual society meetings -- the draft was then submitted to the executive committee of the SIR. Simultaneously, the guidelines were posted on the SIR website. Commentary was invited.
This was accessible to SIR members, that is

interventional radiologists, non-SIR members, and basically anyone working with IVC filters who would like to read about it on the website.
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After the commentary, the comments were collected and

the guidelines draft, plus commentary, was passed on then to the JVIR, which I mentioned is the official journal. And that was reviewed by the editor and his staff among peers.

Q So was the article peer-reviewed before it was published?

A Yes, it was. In addition to our committee reviewing it.

Q And you say it was made accessible to the members of the SIR. Can you tell us approximately how many radiologists -- interventional radiologists belong to the organization?

A Yes. Well, thinking back to the time period of about 2001, at the time of the guidelines, there were over 5,000 members.

Q And in what year were these guidelines published, Doctor?

A They were published in 2001.

Q Does membership in the SIR entitle you to a free subscription to the JVIR?

A It does because members previously received a print version of the journal as well as online access.

Q So would all 5,000-plus members of the Society of Interventional Radiology at the time in 2001 that your guidelines were published, would they have received a copy of the Journal of Vascular and Interventional Radiology

publishing those guidelines?

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A Yes, that's right.
Q Doctor, has the SIR updated those guidelines since 2001?
A Yes, they have.
Q Were the ones that you were the chairperson of the committee and developing, were those republished in 2003?
A That's correct. In what was called a supplement to JVIR, they were published once again.
Q And was the most recent update published in 2017?
A Yes.
Q Dr. Grassi, were the SIR guidelines ever intended to establish acceptable thresholds for IVC filter complications?
A No. The purpose of the committee and of the guidelines document was to educate, inform, and basically summarize information for those working with IVC filters. We felt that by publishing this information it would be very helpful to those practitioners.
Q And what was your committee's expectation as to how the guidelines would be utilized once they were published?
A We intended that they would be a resource to anyone working with IVC filters, and specifically for interventional radiologists it would allow them to look at our numbers, review their own practice, and see, practically speaking, if there was any reason for them to do their own personal quality review and whether it was necessary for them to review their

hours and nine minutes; defendant, 24 hours and 12 minutes. 03:12:14
MR. NORTH: Can I say something on the time, Your Honor? I don't think it needs to be said but I just want to make sure. There was some talk earlier in the trial about if we didn't use all our time, maybe somebody else would get more, but we of course want to reserve that time for our closing and 03:12:33
for punitive damages phase.
THE COURT: I didn't assume you were offering it up.
MR. NORTH: Just wanted to be certain, Your Honor.
THE COURT: Okay. Let's talk about a few issues.
Mr. North, you have been wanting to make a motion. 03:12:53

Why don't we go ahead and deal with that now? 03:12:57
MR. NORTH: So is now the time, Your Honor?
THE COURT: Now is the time.
MR. O'CONNOR: We're going to readjust our dugout.
THE COURT: That's fine. 03:13:09
MR. NORTH: Your Honor, this was the motion that the Court specifically gave us permission to reserve at the end of the plaintiff's case pursuant to Rule 30 and it's timely because it's now at the conclusion of all of the evidence. So

we would be renewing the same motion that we had reserved at that time and two for the price of one, all with one argument, but it's the same motion that we would have articulated at the end of the plaintiff's case and repeat now. 03:13:34

Your Honor, in this case we believe that the evidence is much different than it was at the summary judgment stage. I understand that this court denied summary judgment. But then we don't believe the evidence is the same and, therefore, we would move for judgment, as a matter of law, under Rule 50, both as to the warning claim and as to the claim for punitive damages. 03:13:54 03:14:15

As to the warning claim, there are two issues: The adequacy of the warning and the causation between the warning and the injury to Ms. Booker. The plaintiff's argument at the summary judgment stage was principally focused on evidence of higher complication rates with regard to the G2. They relied 03:14:32

on things like the evidence of Dr. Betensky, the Harvard statistician. That was one of their experts. 03:14:38

They did not bring into this courtroom in this trial evidence of higher complication rates. They assumed higher complication rates in the context of many of their questions. 03:14:53

haven't seen it up on the screen --

THE COURT: Counsel, you have been going for almost 20 minutes. Let's try to wrap this up in the next few if we can. We've got a number of other issues we need to address. 03:37:58 03:38:00

MR. MANKOFF: Sure.

Your Honor, I'll conclude by pointing out that this evidence falls into the categories that you mentioned when you denied the motion for summary judgment. Bard never appropriately tested its devices. They never took action to stop sales of the device when they knew of the problems. They learned of more problems with the EVEREST trial. And at the end of the day, this was about profit. They had marketing and sales, incentive bonuses. There was evidence that they needed a new device in order to maintain and grow market share. They stated that users would be swayed by aggressive marketing, even with negative clinical experience, and they went out and tried to grab a $172 million market. 03:38:26 03:38:45 03:39:07

If there are no further questions, I'll rest.

THE COURT: Okay. Thank you. Give me just a minute.

All right. I've just taken a moment to review my

notes on the D'Ayala testimony. I'm going to deny the motion. I think there is enough evidence for this to go to the jury both on the failure to warn claim and on the punitive damages claim.

All right. Defendants, you want to make a motion; is that right? I'm sorry, plaintiff.

MR. STOLLER: Do you want our motion on judgment, as 03:40:47

a matter of law. 03:40:49

THE COURT: I do and I would like to do this in about five or seven minutes per side.

MR. STOLLER: We've got two. I'll handle the first which is as to the claim by defendants for comparative fault as 03:40:57 to Dr. Amer -- and I'm specifically, Your Honor, going to talk about the element of causation and that they have made no proof of any causation such that they could -- would you like me to do it from here or the podium, Your Honor?

THE COURT: Please. 03:41:19

MR. STOLLER: And I will particularly brief on this one, your Honor.

As you know, they have pointed to Dr. Amer as being a non-party at fault which requires them to demonstrate both that